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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,336	01/20/2006	Ameriga Lazzarini	892,280-499	9155

34263 7590 11/15/2006

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EXAMINER

BRADLEY, CHRISTINA

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/521,336	LAZZARINI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christina Marchetti Bradley	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-42 is/are allowed.
- 6) ☐ Claim(s) 24-28, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/11/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Claims 24-44 are pending; claims 1-23 are cancelled.

#### *Specification*

2. The abstract of the disclosure is objected to because it is not limited to a single paragraph. Correction is required. See MPEP § 608.01(b).

#### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 24-28, 43 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayakawa *et al.* (reference AF cited on Information Disclosure Statement filed 01/11/2005). Hayakawa *et al.* teach fermentation broths from cultures of several strains of *Microbispora* possessing antibiotic activity. The broths were assayed by the conventional paper disc-plate method. As part of this method, the discs would dry resulting in a powder comprising the antibiotic.
5. Hayakawa *et al.* do not teach the physiochemical properties or the chemical structure recited in claims 24-28. Because the fermentation broth taught by Hayakawa *et al.* has the functional properties of the claimed invention and is from the same genus of microorganism, *Microbispora*, there is a reasonable expectation that broth contains the compound of the claimed invention and thus anticipates the claims. The discovery and characterization of properties of a known material do not make it novel (see MPEP § 2112). Furthermore, there is no requirement

Art Unit: 1654

that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference (see MPEP § 2112). Examiner cannot however determine whether or not the composition taught by Hawakawa *et al.* inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See MPEP § 2112.

6. To overcome the rejection, it is suggested that Applicant amend the claims to include the phrase "*An antibiotic 107891... isolated from Microbispora sp. ATCC PTA-5024*" (italics added to indicated changes).

#### ***Double Patenting***

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

8. A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 25 and 26 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3 and 11 of copending Application No. 11/035,296. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

10. Claims 25 and 26 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3 and 16 of copending Application No. 11/045,628. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Art Unit: 1654

11. Claims 27 and 28 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2 and 12 of copending Application No. 11/035,296. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

12. Claims 27 and 28 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2 and 17 of copending Application No. 11/045,628. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

14. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claim 43 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 11 and 12 of copending Application No.

11/035,296. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 43 is generic to all that is recited in claims 2, 3, 11 and 12 of copending Application No. 11/035,296. That is claims 2, 3, 11 and 12 of copending Application

Art Unit: 1654

No. 11/035,296 fall entirely within the scope of claim 43 or, in other words, claim 43 is anticipated by claims 2, 3, 11 and 12 of copending Application No. 11/035,296.

16. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claim 43 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 16 and 17 of copending Application No.

11/045,628. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 43 is generic to all that is recited in claims 2, 3, 16 and 17 of copending Application No. 11/045,628. That is claims 2, 3, 16 and 17 of copending Application No. 11/045,628 fall entirely within the scope of claim 43 or, in other words, claim 43 is anticipated by claims 2, 3, 16 and 17 of copending Application No. 11/045,628.

18. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Allowable Subject Matter***

19. Claims 29-42 are allowable.

#### ***Conclusion***

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571) 272-9044. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

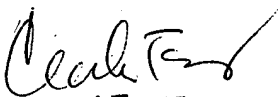
21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

Art Unit: 1654

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Marchetti Bradley, Ph.D.  
Patent Examiner  
Art Unit 1654



Cecilia J. Tsang  
Supervisory Patent Examiner  
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